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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,163	12/21/2001	Audra L. Stinchcomb	ACP-0001	6957
23550	7590	03/02/2004	EXAMINER	
HOFFMAN WARNICK & D'ALESSANDRO, LLC			GHALI, ISIS A D	
3 E-COMM SQUARE			ART UNIT	PAPER NUMBER
ALBANY, NY 12207			1615	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/032,163	Applicant(s) STINCHCOMB, AUDRA L.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is FINAL.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8-10 and 12-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8-10, 29, 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The receipt is acknowledged of applicant's amendment, filed 12/22/2003.

Claims 1, 7 and 11 have been canceled; claims 29 and 30 have been added per applicant's amendment filed 12/22/2003.

1. This application contains claims 12-28 drawn to an invention nonelected with traverse in Paper filed 07/09/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

**Claims 2-6, 8-10, 29, and 30 are included in the prosecution.**

#### **The standing rejections:**

##### **(A) *Claim Rejections - 35 USC § 102***

Claims 2-6, 8-9, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,328,992 ('992).

US '992 disclosed transdermal structure for delivering cannabis for the treatment of nausea and pain associated with cancer chemotherapy and wasting associated with AIDS, that reads on claims 1 and 6 (abstract; col.1, lines 24-30). Cannabis means any

one or more or mixture of compounds or chemical components including delta 8THC, delta 9 THC, cannabinal, cannabidiol, that reads on claims 1 and 7 (col.2, lines 47-53; col.7, lines 54-58). The transdermal structure comprises patches, bandages or covering, that reads on claims 8 and 9 (col.1, lines 58-60). The patch is occlusive and comprises backing layer; rate controlling membrane; reservoir positioned between the backing and the rate controlling membrane and comprises the active agent in a suitable carrier; and an adhesive means, that reads on claims 2, 3, and 5 (col.2, lines 6-10, 21-24; col.3, lines 4-8, 25-28, 49-51, 64-67; col.4, lines 66-67; col.5, line 1). The suitable carrier includes gel, that reads on claim 4 (col.3, lines 37-45).

The limitations of claims 1-9 are met by the US '992 reference.

**(B) Claim Rejections - 35 USC § 103**

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '992 in view of PGPB 2003/0158191 ('191).

The teachings US '992 are discussed under 102 rejection above.

The reference does not teach the inclusion of opiate with the transdermal delivery of cannabis derivatives.

PGPB '191 teaches a combination of cannabis derivatives delivered transdermally with other active agents including morphine page 2, 0012; page 10, 0214; page 14, 0356; page 15, 0359, 0362). The reference teaches that the combination therapy may allow for increased efficacy and potentially reduces side effects (page 16, 0370).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cannabis derivatives delivered transdermally as taught by US '992 and add opiate in the transdermal system as taught by PGPB '191, motivated by the teaching of PGPB '191 that the combination therapy may allow for facilitating increased efficacy and potentially reduces side effects, with reasonable expectation of having a device that delivers cannabis derivatives and opiate with increased efficacy and reduced side effects.

### ***Response to Arguments***

2. Applicant's arguments filed 12/22/2003 have been fully considered but they are not persuasive.

Applicant traverses the rejection of claims 1-9 as being anticipated by US '992 by arguing that US '992 does not teach transdermal delivery of a composition consisting essentially of CBD, but teaches administration of a mixture of cannabinoids. Further, the subject matter of the claims under consideration, as amended, is not anticipated by and could not have been obvious over US '992 alone or in combination with US '191 because they teach the administration of the mixture of cannabinoids, and different compounds can have different effect on transdermal delivery of other compounds and one can not predict with reasonable degree of success how different compounds will behave when administered alone based on how they behave when administered in combination.

In response to the above arguments, the examiner position is that the claims as amended still anticipated by US '992 because the reference disclosed the transdermal administration of cannabinoid mixture including cannabidiol (CBD). The expression "consisting essentially of" does not exclude the presence of other components that does not materially alter the composition, and the "cannabidiol" encompasses more than one compound as disclosed by applicant on page 7 of the present specification. The reference choice to combine CBD with other cannabinoids does not make the present claims patentable. The art recognized the transdermal administration of composition comprising CBD to relieve the symptoms associated with cancer chemotherapy and wasting associated with HIV infection. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. US '191 is relied upon for teaching of administration of a combination of the cannabinoid with opioid.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are

evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

### ***Conclusion***

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

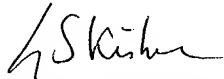
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1615

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